

## REMARKS/ARGUMENTS

Claims 63, 66, and 72 are under examination. Claims 1-38 and 64-65 had previously been canceled without prejudice. Claims 39-62, 67-71, and 73-84 have been canceled in this Amendment as non-elected claims. Claims 63 and 72 have been amended to better claim the subject matter which Applicants regard as the invention and for improved clarity. Support is found in the specification at page 15. Applicants reserve the right to file one or more divisional and/or continuation applications to pursue the subject matter of the canceled claims. No new matter has been introduced in this Amendment.

### Claim Rejections under 35 U.S.C. 112:

Claims 63, 66, and 72 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not meeting the requirements of written description and enablement.

Without acquiescing to this rejection and in the interest of advancing prosecution of this application, claims 63 and 72 have been amended to delete the phrase, "or a functional fragment thereof of at least 20 amino acids in length which shows immunological cross-reactivity with said polypeptide". Claim 72 has been further amended to recite a fragment which can be used to generate antibodies which specifically recognize the polypeptide whose amino acid sequence is shown in SEQ ID NO:5. Regarding the amendments made in claim 72, Applicants provide the following comments.

The present inventors are the first to isolate the nucleic acid molecule encoding the *Moraxella bovis* polypeptide as set forth in SEQ ID NO: 5. This discovery made it possible for those skilled in the art to generate antibodies specific for this polypeptide. It is well known in the art that specific antibodies against a given polypeptide can be generated by employing an intact polypeptide as well as various peptide fragments derived from the intact polypeptide. Once the amino acid sequence encoding a polypeptide is known, it is routine in the art to synthesize a series of overlapping peptides and immunize an animal and screen for those antibodies which provide specificity and selectivity for the given polypeptide. In fact, the technologies necessary for producing antibodies have become largely automated

in recent years. The present Specification provides a detailed description regarding antibody production and adjuvants and carriers including several key references relevant for this subject matter at pages 11-13.

Based on the foregoing, Applicants maintain that claims 63, 66, and 72 as amended are sufficiently described and enabled based on the present disclosure and the knowledge and information readily available in the art.

Claim Rejections under 35 U.S.C. 102:

Claims 63, 66, and 72 are rejected under 35 U.S.C. 102 as allegedly anticipated by Campos et al. (USPN 6,096,320) and Billson et al. (FEMS Microbiology 1994 124:69-73). Applicants respectfully traverse this rejection.

Without acquiescing to this rejection, the claims at issue have been amended in the present Amendment. With entry of this Amendment, claims 63, 66, and 72 are considered to be allowable. Applicants provide the following response regarding the issues raised by the Examiner.

Applicants maintain that claims 63, 66, and 72 are not anticipated by either Campos et al. or Billson et al. It is well established that for a reference to anticipate a claim it must disclose each and every element of the claim. MPEP 2131.

Campos et al. discloses the nucleotide and amino acid sequences of leukotoxin derived from *Pasteurella haemolytica*. This protein contains regions that are homologous with the sequence of the *M. bovis* polypeptide disclosed herein. However, amended claim 72 specifically recites that the antibodies generated against a fragment derived from the *M. bovis* polypeptide be specific for recognizing the *M. bovis* polypeptide. This limitation excludes any fragments derived from SEQ ID NO:5 which would produce antibodies that are cross-reactive with other proteins such as leukotoxin disclosed by Campos et al. The amendments made in claim 72 is intended to define an immunogenic composition to raise

an immune response that is specific and selective for the *M. bovis* polypeptide whose sequence is given in SEQ ID NO:5.

The Office Action states on page 9 that "... the prior art also discloses isolated polypeptide (recombinant polypeptide P. haemolytica leukotoxin) and a composition comprising said peptide in phosphate buffered saline (i.e., carrier with Emulsigen as the adjuvant) and thus read on composition claim 72. Thus the prior art anticipated the claimed invention."

Applicants do not agree. Applicants emphasize that anticipating references must teach each and every element of the claimed invention. The *M. bovis* polypeptide of SEQ ID NO:5 recited in claim 72 is not leukotoxin disclosed in the cited reference. A fragment derived from the *M. bovis* polypeptide which can produce specific and selective antibodies against the polypeptide of SEQ ID NO:5 is not taught by Campos et al.

The Office Action further alleges that Billson et al. disclose an isolated recombinant haemolysin antigen and a vaccine composition comprising said haemolysin antigen from the haemolytic strain *M. bovis* isolate UQV 148NF.

Billson et al. does not disclose an isolated recombinant haemolysin antigen of *M. bovis* isolate UQV 148NF. Only a "partially purified cell-free preparation" from this strain was used in Billson et al. studies. The present inventors employed a different isolate of *M. bovis* strain, Dalton 2d, to obtain the sequence for the polypeptide claimed. Billson et al. does not teach a substantially purified polypeptide whose sequence is shown in SEQ ID NO:5 or a fragment derived therefrom. In fact, there is no information regarding the composition or sequence of the partially purified cell-free preparation described in Billson et al. Those skilled in the art would not have been able to use the polypeptide of SEQ ID NO:5 or any fragments derived from that polypeptide to raise an immune response based on Billson et al.

In summary, claims 63, 66, and 72 are not anticipated by either Campos et al. or Billson et al. Withdrawal of the rejection under 35 U.S.C. 102(b) is respectfully requested.

Conclusion:

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are further issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Petition for Extension of Time (two months) and a check in the amount of \$450 as required under 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please deduct from Deposit Account No. 07-1969 the appropriate fee for this submission and any extension of time required.

Respectfully submitted,



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March 18, 2005